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TOWNSEND and TOWNSEND and CREW LLP

By: Sharen Sivins

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Lawrence Salkoff *et al.*

Application No.: 09/519,076

Filed: March 6, 2000

For: PH SENSITIVE POTASSIUM
CHANNEL IN SPERMATOCYTES

Examiner: Nirmal S. Basi

Art Unit: 1646

DECLARATION UNDER 37 C.F.R.
§ 1.132 OF DR. TIMOTHY JEGLA

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Timothy Jegla, Ph.D., being duly warned that willful false statements and the like are punishable by fine or imprisonment or both (18 U.S.C. § 1001), and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true, and statements made on information or belief are believed to be true and correct.

2. I received a B.S. in Biology from Carleton College in 1990. I received a Ph.D. in 1996 from the Department of Anatomy and Neurobiology, Washington University. From 1996 to 1997, I was a postdoctoral fellow in the Department of Molecular and Cellular Physiology, Howard Hughes Medical Institute, Stanford University.

3. I have been employed at ICAgen, Inc. since 1997. From 1997 to 1999, I was a Senior Scientist in the Department of Molecular Biology. From 1999 to 2000, I was a Program Scientist, Head of Molecular Sciences, Department to Molecular Biology. Since 2000, I have been the Chief Scientist, Head of Molecular Sciences.

4. The present invention provides for the first time Slo3, a pH sensitive potassium channel expressed in spermatocytes.

5. I am an employee of ICAgen, Inc., which is a co-assignee and licensee of the above-referenced patent application. I have read and am familiar with the contents of the patent application. In addition, I have read the Office Action, mailed October 23, 2001, received in the present case. It is my understanding that the Examiner believes that this invention is supported by neither a specific, substantial, and credible asserted utility nor a well established utility as required by the United States Patent Laws.

6. This application claims isolated polypeptide monomers of a Slo3 potassium channel expressed in spermatocytes that is activated by changes in intracellular pH and membrane potential.

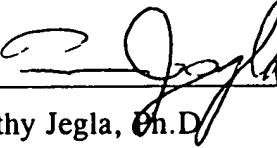
7. This declaration is provided to demonstrate that, at the time the application was filed, one of skill in the art would recognize the utility of the present invention and would appreciate its real world context.

8. It is well known that intracellular pH has a profound effect on the viability of mammalian sperm. For example, alkaline pH is necessary for sperm capacitation and the acrosome reaction (Arnoult *et al.*, *J. Cell. Biol.* 134:637-645 (1996); Zeng *et al.*, *Dev. Biol.* 173:510-520 (1996) (attached hereto as Exhibits A and B). Sperm capacitation refers to the change undergone by sperm in the female reproductive tract that enables the sperm to penetrate and fertilize an egg. Sperm capacitation is known to be accompanied by increases in potassium permeability that hyperpolarizes the membrane. Because the newly identified Slo3 is highly and specifically expressed in sperm and is activated by alkalinization, those of skill in the art would expect that the Slo3 channel plays an important role in sperm capacitation, e.g., by increasing potassium permeability.

9. It would be apparent to anyone of skill in the art that Slo3 is an excellent target for candidate compounds that modulate sperm function. Assays for such compounds, using Slo3 as a target, are useful for identifying compounds that affect fertility. For example, Slo3 openers could be used to initiate the capacitation cascade. A Slo3 opener, therefore, could be used to treat certain types of infertility caused by reduced sperm function. Conversely, Slo3 blockers could block capacitation and the acrosome reaction. A Slo3 blocker, therefore, could be useful as a contraceptive device.

10. In view of the foregoing, it is my scientific opinion that one of skill in the art, at the time the application was filed, would immediately recognize the real world utility of the polypeptide monomers of this invention. Therefore, this invention is supported by a specific, substantial, and credible utility.

Date: 11/6/02

By: 

Timothy Jegla, Ph.D.